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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,138	11/25/2002	Saliha Moussaoui -Mrabet	ST99040 US PCT	1464

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ROSS J. OEHLER
SANOFI-AVENTIS U.S. LLC
1041 ROUTE 202-206
MAIL CODE: D303A
BRIDGEWATER, NJ 08807

EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

NOTIFICATION DATE	DELIVERY MODE
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07/27/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPatent.E-Filing@sanofi-aventis.com
andrea.ryan@sanofi-aventis.com

Office Action Summary

Application No.

10/088,138

Applicant(s)

MOUSSAOUI -MRABET ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,13,15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,13,15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/22/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed May 15, 2007 (hereinafter referred to as "the response") has been entered. Claims 1 and 4 have been amended and Claims 15 and 16 have been newly added. Claims 11, 12, and 14 have been cancelled.

Accordingly, Claims 1-10, 13, 15, and 16 are pending in the instant application.

The elected invention is drawn to (i) a non-human transgenic animal model of Alzheimer's disease which exhibits both amyloid plaques and mitochondrial dysfunction, and (ii) a method for identifying compounds for treating neurodegenerative diseases using the transgenic animal model. Applicants further elected the M146L mutation of PS1 and an APP gene comprising the combination of Swedish, London, and Dutch mutations.

Claims 1-10, 13, 15, and 16 are examined herein.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1-10 and 13 stand rejected and Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 98/17782 (Duff et al., published April 30, 1998).

Duff et al. (1998) disclose a transgenic mouse comprising a PS1 gene having the M146L mutation and further comprising an APP gene of the APP695 isoform having the mutations K670N and M671L (Swedish mutation). The double transgenic mice exhibit amyloid plaques (see Table 1 at page 23) and behavioral deficits consistent with an Alzheimer's disease model. The reference is silent with regard to a mitochondrial dysfunction and neuronal death/loss. However, when the structure disclosed in the prior art is substantially identical to that claimed, claimed properties are presumed inherent.

MPEP § 2112(III) states that a rejection under 35 U.S.C. 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic. Here, the prior art is silent with respect to mitochondrial dysfunction and neuronal death/loss.

The MPEP states that the "express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103." MPEP § 2112. Also see the decision of *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) which states that "[t]he inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." The MPEP further emphasizes that the "inherent feature need not be recognized at the time of the invention" (MPEP § 2112).

MPEP § 2112 explicitly states the following:

"SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

'The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer.' *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)."

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The MPEP further teaches that “once a reference teaching product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference.” MPEP § 2112. In the instant case, no evidence has been presented to show that the prior art product does not necessarily or inherently possess the characteristics of the claimed animal.

In the decision of *In re Spada*, 15 USPQ2d 1655 (CAFC 1990) the court points out that discovery of a new property or use of a previously known composition, even if unobvious from prior art, cannot impart patentability to claims to known compositions. The transgenic animal claimed constitutes “a previously known composition.”

Thus, the claimed invention is disclosed in the prior art.

At page 4 of the response, Applicants assert that there is no basis to believe that the mitochondrial dysfunction disclosed in the instant invention is an inherent feature of Duff et al. Applicants contend that the transgenic animals of the instant invention exhibit neuronal loss, which is not characteristic of the transgenic mice disclosed by Duff et al., and that the transgenic mice of Duff et al. exhibit amyloid deposition, reactive astrocytes and behavioral deficits. Applicants point out that Duff et al. notes that the behavioral deficits did not correlate with the deposition of A β , suggesting that these deficits of cognitive impairment are not entirely related to a toxic component of visible amyloid deposits. Applicants cite Takeuchi et al. (2000) for their further characterization of the mice of Duff et al. to look for neuronal loss. Applicants note that Takeuchi et al. reported observing no neuronal loss. Applicants therefore conclude that the mouse of Duff et al. does not have all the characteristics of the animal instantly claimed. Applicants further assert that since they don't display neuronal loss, there is no basis to believe that the mice of Duff et al. would exhibit mitochondrial dysfunction. However, while the Takeuchi reference reports looking for neuronal degeneration, it does not report any experiments that look at mitochondrial function and therefore, this reference, like Duff et al., is silent with regard to mitochondrial function.

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Furthermore, the reference does report some level of neuronal loss, while noting that it is not dramatic neuronal loss (see abstract). Thus, the mice of Duff et al. meet the claim limitations. The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 USPQ 1302, 1303 (BPAI 1993), *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ2d 1922, 1923 (BPAI 1989). When the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent. See MPEP 2112.01 and *In re Best*, 195 USPQ 430, 433 (CCPA 1997). Here, the mice disclosed by Duff et al. are substantially identical to the mice instantly claimed.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on (571) 272-4517. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

/Anne-Marie Falk/
Primary Examiner, Art Unit 1632